REMARKS

Claims 1-36 are pending in this application. Claim 37 is newly added herein. Upon entry of this amendment, claims 1-37 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for new claim 37 may be found in claim 19 and in the specification at page 50, lines 1-10.

Claims 1-18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543). For the purpose of examination, Baba et al. (US 6,638,991) was used as the English translation of Bata et al. (WO 01/171415). (Office action p. 2)

Claims 19-26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543). For the purpose of examination, Baba et al. (US 6,638,991) was used as the English translation of Bata et al. (WO 01/171415). (Office action p. 5)

Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Valiant, JR. et al. (US 2002/0102415). For the purpose of examination, Baba

et al. (US 6,638,991) was used as the English translation of Bata et al. (WO 01/171415). (Office action p. 6)

Claim 28 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Hayashi et al. (US 6,503,632). For the purpose of examination, Baba et al. (US 6,638,991) was used as the English translation of Bata et al. (WO 01/171415). (Office action p. 7)

Claims 29-30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Walther et al. (US 6,379,004). For the purpose of examination, Baba et al. (US 6,638,991) was used as the English translation of Bata et al. (WO 01/171415). (Office action p. 8)

Claims 31-35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 26 above, and further in view of Turek et al. (US 2002/0137811). For the purpose of examination, Baba et al. (US 6,638,991) was used as the English translation of Bata et al. (WO 01/171415). (Office action p. 9)

Claim 36 is rejected under 35 U.S.C. §103(a) as being unpatentable over Baba et al. (WO 01/171415) in view of Shibata et al. (US 4,547,543), as applied to claim 19 above, and

further in view of Niwa et al. (US 5,516,467). For the purpose of examination, Baba et al. (US 6,638,991) was used as the English translation of Bata et al. (WO 01/171415). (Office action p. 8)

Reconsideration of the rejections of claims 1-36 is respectfully requested.

Regarding Shibata et al.

Shibata et al. discloses that 1,3-MMP has a superior copolymerazability with other monomers, but the target of the copolymerization with N-MMP is only alkyl acrylate or methacrylate, which are added for the purpose of adding mechanical strength to lens material (column 2, line 25-26). There is no suggestion for copolymerization with silicone compounds, such as are used in present invention.

Therefore, the Dk of the ocular lens material obtained by the present invention becomes not less than 51, but the Dk of the ocular lens material obtained by Shibata et al. becomes absolutely lower such as 23-43.

The goal of Shibata is a hydro gel which has a water content not less than 55.8% by weight, and Applicant infers that Shibata et al. uses the 1,3-MMP to improve their copolymerizability with alkyl acrylate or methacrylate, which are added for the purpose of adding mechanical strength to the lens material. In other words, it is understood for us that 1,3-MMP is used as "an auxiliary monomer" to enhance the effect of N-VP and not used as an alternate compound to N-VP. The ocular lens material of Shibata et al is manufactured based on this concept.

Table.1 Comparison between the present invention and Shibata's invention

	the present invention	invention of Shibata et al
oxygen permeability (Dk)	not less than 51	23-43
water content	not more than 55%	not less than 55.8%

Regarding Baba et al.'991

In the Baba et al. reference, for the purpose of making a silicone hydrogel lens which essentially contains N-VP, it is described that a lens that has superior surface wettability and mechanical property is obtained by exactly controlling the content of monomer and crosslinking agent.

It is also disclosed that:

> "On the other hand, when N-vinylpyrrolidone (C-1) is not used, desirable low frictional property, lubricity and stain resistance cannot be imparted to the ocular lens material. From these facts, it is essential to use N-vinylpyrrolidone (C-1) and the hydrophilic monomer (C-2) together, and the polymerizable group in the hydrophilic monomer (C-2) is acryloyl group, vinyl group or allyl group in consideration of copolymerizability with N-vinylpyrrolidone (C-1)" (Column 9, lines 34-42).

On the contrary, it is described in the present specification that using a 1,3-MMP as an alternative compound to N-VP can decrease the residual monomer drastically while keeping excellent properties of N-VP such as superior hydrophilic property and wettability for the purpose of making a silicone hydrogel lens (Compared Ex. 1 (Table 1-3) to Com. Ex. 1 (Table 1-3), and Compared Ex. 17 (Table 6, 11) to Com. Ex. 2 (Table 2, 12)).

And as shown in Table 4, the non-polymerized polymer is eluted in the series of "silicone + N-VP" even after the extraction by water, but the quantity of elution becomes drastically reduced by using 1,3-MMP.

Table 2. Comparison between the present invention and Baba's invention

	Example 1 of the present invention	Comparative Example 1 of the present invention (corresponding to Baba et al)
residual monomer (%)	0.2	1.0
elution amount of TOC (ppmC, 14 days after sterilization)	4.8	11.8

The effects of this are to simplify the step of extraction to decrease the residual monomer, to reduce the quantity of polymer elution after the sterilization, to obtain a contact lens which has a high safe property, is industry applicable, and has a beneficial effect.

For the purpose of making a silicone hydrogel lens, the fact that the above effect in manufacturing occurs by using a specific combination of monomers, that is silicone macromer (A) and pyrrolidone derivative, is not disclosed or suggested by Baba et al.

The ocular lens material obtained by the present invention has not only excellent lubricity and surface wettability. This property is clearly understood by comparing Example 17 and Comparative Example 2. The results of the feeling test and Contact angle, which are reference marks of lubricity and wettability, are at the same level, but the result of tensile modulus, which is

reference mark of softness of the present invention, becomes absolutely lower than Baba et al. It is clear that the ocular lens material of the present invention can provide a contact lens which has high safety and good comfortability.

Table 3. Comparison between the present invention and Baba's invention (material characteristics, from Table 11 and 12 of the present invention)

	Example 17 of the present invention	Comparative Example 2 of the present invention (corresponding to Baba et al)
composition		
TRIS	25	25
macromonomer A	25	25
DMAA	12.5	12.5
1,3-MMP	37.5	-
N-VP	-	37.5
feeling test	A	A
contact angle	22	22
tensile modulus (MPa)	0.23	0.47

The superior effects of the present invention are not obvious over the teachings and Examples of Baba et al.

Considering all the factors together, there is no suggestion in the cited references that a contact lens material that has high safety, superior surface property and mechanical property with low elution amount would be obtained by using 1,3-MMP as an alternate compound of N-VP.

Applicant therefore submits that the pending claims are not obvious over the cited references, taken separately or in combination.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants' undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

KRATZ, QUINTOS & HANSON, LLP

Daniel A. Geselowitz, Ph.D.
Agent for Applicants
Reg. No. 42,573

DAG/xl

Atty. Docket No. **050443**
Suite 400
1420 K Street, N.W.
Washington, D.C. 20005
(202) 659-2930

23850
PATENT & TRADEMARK OFFICE

Enclosures: Amendment Fee Transmittal
Petition for Extension of Time

H:\050\050443\Response in re FOA of 07-28-08